February 28, 2022

John Ohaniain
Director, Center for Data Insights and Innovation
via email: John.Ohanian@chss.ca.gov

Re: Comments on the DxF Data Sharing Agreement Draft Language – First Set of Topics (v1)

John:

On behalf of the undersigned organizations, thank you for the opportunity to comment on the DxF Data Sharing Agreement (DSA) Draft Language – First Set of Topics[1]. Our thoughts on the draft document are divided into two sections – an overarching comment, and some thoughts and questions on several specific components of the draft language.

As always, we appreciate the work that you and your team are doing to make the DxF a reality, and we stand ready to work with CDII to refine the DSA as it moves forward.

Overarching comment: Much of this language appears to have been adapted from the California Data Use and Reciprocal Support Agreement (CalDURSA). That document has a different audience and serves a very different purpose from the DSA.

It is apparent from a side-by-side comparison that much of the language in the DSA has been adapted from the CalDURSA[2], which itself was adapted from the DURSA created by the eHealth Exchange[3]. We understand and support the idea of using these existing documents as guides for the structure of the DSA. However, we ask CDII and the Subcommittee to remember that the CalDURSA was created as a voluntary agreement between a limited number of health information organizations (HIOs).

The DSA, on the other hand, is a document that thousands of participants will be legally required to sign. The language and the legal structure of the agreement must be looked at very differently with that in mind. For example, the document references "the Committee." In the CalDURSA, that references the California Interoperability Committee (CIC). It is unclear what entity that would be referencing in the DSA. Also, there are currently 18 signatories to the CalDURSA, making it possible for them to coordinate amongst themselves. The same cannot be said for thousands of health care providers statewide.

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[1] As there may be multiple versions of this document, these comments are applicable to the version accessed at https://www.chhs.ca.gov/data-exchange-framework/#data-sharing-agreement-subcommittee-2022-meeting-materials as of February 17, 2022.
[2] https://www.ca-hie.org/initiatives/cten/caldursa/
[3] https://ehealthexchange.org/dursa/#:~:text=The%20DURSA%20is%20a%20comprehensive,as%20part%20of%20eHealth%20Exchange.

Furthermore, there are multiple places in the document (see below) that would create requirements on providers that exceed those created by HIPAA and CMIA. Such requirements may be acceptable in a voluntary agreement between HIOs, but are not allowed by the statute governing the DxF.

AB 133 stipulates that:

> *(3) The California Health and Human Services Data Exchange Framework shall align with state and federal data requirements, including the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), the Confidentiality of Medical Information Act of 1996 (Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code), and other applicable state and federal privacy laws related to the sharing of data among and between providers, payers, and the government, while also streamlining and reducing reporting burden.*
> [HSC §130290(a)(3)]

The DSA is not allowed to invent new law that would exceed existing state and federal privacy statutes.

<u>Specific Comments</u>

Subsection 12.5 Breach Notification

Comment #1 – The Breach Notification requirements exceed HIPAA and CMIA
Per this subsection, a physician would have to provide a breach notification no later than 2 calendar days after determining it has occurred. This is incongruent with HIPAA requirements (no later than 60 days 45 CFR §164.404) and California law (no later than 15 days, HSC §1280.15).

Comment #2 – "Participant" needs to be defined
This subsection references "participants" who need to be notified in the event of a breach. This language made sense in the CalDURSA, where there are a limited number of signatories. The DSA will be signed by thousands of entities. This subsection needs to define better who is to be notified. We suggest limiting who should be notified to be consistent with the requirement of HSC §1280.15.

Comment #3 – Content of the Breach Notification exceeds existing law
The contents of the notification here go further than current CA law. Rather than imposing another set of breach notification standards, we suggest deleting this section and ending it with the last sentence. ("The notification should include sufficient information for the recipient of the notification to understand the nature of the Breach"). CDPH regulations already stipulate the required content for a breach notification.

Subsection 12.6

Comment – A one hour notification requirement is not feasible
We believe that the one hour rule may have been adopted from a proposed federal rule. If so, federal HHS actually dropped the proposal because it was unfeasible, even for very large entities. Small and safety net practices have no hope of complying with a one hour standard.

Subsection 12.7 – Law Enforcement Exception

Comment – Define the section of law that governs this requirement
HIPAA and state law limit the amount of time a notification can be delayed, and the timeframes are

different under state law based on whether the request was made orally or in writing. *See* 45 CFR §164.512; Health & Safety Code §1280.15. It needs to be clarified which law will govern this section.

Definition of "Exchange Purposes"

Comment – Remove outdated language referencing "Meaningful Use"
In Purpose #7, there are references to "Meaningful Use" of certified electronic health record technology. The federal government stopped using that term in April 2018, instead calling it "Promoting Interoperability." To avoid any such outdated language, we recommend that this purpose be deleted and rewritten as:

> 7. Collecting and/or reporting data required by any state or federally-mandated quality improvement program.

Subsection 14.2

Comment #1 – Reorder this section to define clearly the obligations of each party
The way this section is currently constructed, it is difficult to follow the obligations on each party. We Recommend restructuring this entire section to outline the obligations of each party, e.g.:

> 14.2 The requesting Participant shall…..
>
> 14.3 The recipient Participant shall …….
>
> 14.4 (If applicable, the requirements on any Participants, besides the original recipient, who must be responsive to a request.)

Comment #2 – Define the limits of the indemnification provided by this subsection **–** the indemnification language contains no limitations on a party's exposure to liability. Thus, a participant who provides assurances that an authorization is legally valid could be exposed to potential liability for an indefinite amount of money over an indefinite period of time. Given that no participant is required to provide assurances that an authorization is legally valid, there seems to be no incentive for any party to willingly expose themselves to such broad and uncapped liability.

Thank you in advance for your consideration of our comments. We look forward to continuing to work with you as this document progresses.

Signed,

The California Medical Association
America's Physician Groups
California Association of Health Facilities
California Primary Care Association